

## § 201.58

(1) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning an indication for use of the drug, the reference shall be based upon, or the clinical study shall constitute, an adequate and well-controlled clinical investigation under § 314.126(b) of this chapter.

(2) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks shall also be identified or discussed in the appropriate section of the labeling for the drug.

[44 FR 37462, June 26, 1979, as amended at 55 FR 11576, Mar. 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

## § 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under § 201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of § 314.126(b) of this chapter shall be submitted in writing as provided in § 314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20587, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990]

## 21 CFR Ch. I (4–1–03 Edition)

## § 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

(a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §§ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the requirements set forth in the regulations, with the following exceptions:

(1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.

(2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

(3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

Effective	Revised labeling due	Drug class	Mail routing code
BIOLOGICS			
Nov. 1, 1982	Nov. 1, 1980	Bacterial vaccines and antigens with no U.S. standard of potency.	HFB-240
Do .....	.....do .....	Skin test antigens .....	HFB-240
Nov. 1, 1982 <sup>1</sup>	Nov. 1, 1980 <sup>2</sup>	Bacterial vaccines and toxoids with standards of potency. ....	HFB-240
Do .....	.....do .....	Viral and rickettsial vaccines .....	HFB-240
Do .....	.....do .....	Allergenic extracts .....	HFB-240
Do .....	.....do .....	Blood and blood derivatives .....	HFB-240
NEW DRUGS AND ANTIBIOTIC DRUGS			
Nov. 1, 1982	Nov. 1, 1980	Antiarrhythmics .....	HFD-110
Do .....	.....do .....	Replenishers and regulators of electrolytes and water balance ...	HFD-110, HFD-510, and
			HFD-160
Do .....	.....do .....	Anticonvulsants .....	HFD-120

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Effective	Revised labeling due	Drug class	Mail routing code
Do .....	.....do .....	Adrenal corticosteroids .....	HFD-510 and HFD-150
Do .....	.....do .....	Aminoglycosides .....	HFD-520
Do .....	.....do .....	Scabicides .....	Do.
Do .....	.....do .....	Pediculicides .....	Do.
Do .....	.....do .....	General anesthetics .....	HFD-160
Dec. 1, 1982 ..	Dec. 1, 1980 ..	Antivirals .....	HFD-520
Do .....	.....do .....	Dermatologics .....	Do.
Jan. 1, 1983 ..	Jan. 1, 1981 ..	Glaucoma ophthalmics .....	HFD-520
Do .....	.....do .....	Topical otics .....	Do.
Feb. 1, 1983 ..	Feb. 1, 1981 ..	Antispasmodics .....	HFD-110
Do .....	.....do .....	Anticholinergics .....	Do.
Do .....	.....do .....	Diuretics .....	Do.
Do .....	.....do .....	Narcotic antagonists .....	HFD-120
Do .....	.....do .....	Alcohol antagonists .....	Do.
Do .....	.....do .....	Antipsychotics/antimanics .....	Do.
Do .....	.....do .....	Androgens .....	HFD-510
Do .....	.....do .....	Anabolic steroids .....	Do.
Do .....	.....do .....	Hyperlipidemia .....	Do.
Do .....	.....do .....	Anthelmintics .....	HFD-520
Do .....	.....do .....	Antigout .....	HFD-150
Mar. 1, 1983 ..	Mar. 1, 1981 ..	Vaginal antibiotics .....	HFD-520
Apr. 1, 1983 ..	Apr. 1, 1981 ..	Cephalosporins .....	HFD-520
May 1, 1983 ..	May 1, 1981 ..	General analgesics .....	HFD-120
Do .....	.....do .....	Anterior pituitary hormones .....	HFD-510
Do .....	.....do .....	Hypothalamic hormones .....	Do.
Do .....	.....do .....	Progestins .....	Do.
Do .....	.....do .....	Mydriatic ophthalmics .....	HFD-520
Do .....	.....do .....	Cycloplegic ophthalmics .....	Do.
Do .....	.....do .....	Radiopharmaceuticals, diagnostic .....	HFD-150
Do .....	.....do .....	Radiopharmaceuticals, therapeutic .....	Do.
Do .....	.....do .....	Contrast agents diagnostic radiopaque .....	Do.
Do .....	.....do .....	Local anesthetics .....	HFD-160
Do .....	.....do .....	Antihistamines .....	Do.
June 1, 1983 ..	June 1, 1981 ..	Antifungals .....	HFD-520
July 1, 1983 ..	July 1, 1981 ..	Antidiarrheals .....	HFD-110
Do .....	.....do .....	Cardiac glycosides .....	Do.
Do .....	.....do .....	Sedatives .....	HFD-120
Do .....	.....do .....	Hypnotics .....	Do.
Do .....	.....do .....	Tetracyclines .....	HFD-520
Aug. 1, 1983 ..	Aug. 1, 1981 ..	Calcium metabolism .....	HFD-510
Do .....	.....do .....	Vitamins and minerals .....	Do.
Do .....	.....do .....	Antiinfective ophthalmics .....	HFD-520
Do .....	.....do .....	Antiinflammatory ophthalmics .....	Do.
Sept. 1, 1983 ..	Sept. 1, 1981 ..	Antihypertensives .....	HFD-110
Do .....	.....do .....	Drugs indicated for extrapyramidal movement disorders .....	HFD-120
Do .....	.....do .....	Antiprotozoals .....	HFD-520
Oct. 1, 1983 ..	Oct. 1, 1981 ..	Penicillins .....	HFD-520
Nov. 1, 1983 ..	Nov. 1, 1981 ..	Blood glucose regulators (except sulfonylureas) .....	HFD-510
Oct. 9, 1984 ..	July 10, 1984 ..	Sulfonylurea blood glucose regulators .....	HFN-130
Nov. 1, 1983 ..	Nov. 1, 1981 ..	Drugs indicated for parenteral nutrition .....	HFD-510 and HFD-160
Do .....	.....do .....	Drugs indicated for enteral nutrition .....	Do.
Do .....	.....do .....	Miscellaneous ophthalmics .....	HFD-520
Do .....	.....do .....	Immunomodulators .....	HFD-150
Dec. 1, 1983 ..	Dec. 1, 1981 ..	Anticoagulants .....	HFD-110
Do .....	.....do .....	Thrombolytics .....	Do.
Do .....	.....do .....	Drugs indicated for acid peptic disorders .....	Do.
Do .....	.....do .....	Antidepressants .....	HFD-120
Do .....	.....do .....	Drugs indicated for skeletal muscle hyperactivity .....	Do.
Do .....	.....do .....	Sulfonamides and related sulfa compounds .....	HFD-520
Do .....	.....do .....	Dental preparations .....	HFD-160
Jan. 1, 1984 ..	Jan. 1, 1982 ..	Miscellaneous antibacterials .....	HFD-520
Feb. 1, 1984 ..	Feb. 1, 1982 ..	Drugs indicated for infertility .....	HFD-510
Do .....	.....do .....	Thyroids .....	Do.
Do .....	.....do .....	Antithyroids .....	Do.
Do .....	.....do .....	Polymyxins .....	HFD-520
Do .....	.....do .....	Antineoplastics .....	HFD-150
Mar. 1, 1984 ..	Mar. 1, 1982 ..	Urinary tract stimulants .....	HFD-110
Do .....	.....do .....	Urinary tract relaxants .....	Do.
Do .....	.....do .....	Antimigraine .....	HFD-120
Do .....	.....do .....	Antimycobacterials (including antileprosy) .....	HFD-520
Do .....	.....do .....	Adjuncts to anesthesia .....	HFD-160
Apr. 1, 1984 ..	Apr. 1, 1982 ..	Antianginals .....	HFD-110
Do .....	.....do .....	Laxatives .....	Do.

Effective	Revised labeling due	Drug class	Mail routing code
Do .....	.....do .....	CNS stimulants .....	HFD-120
Do .....	.....do .....	Anorexiant .....	Do.
Do .....	.....do .....	Chloramphenicol and derivatives .....	HFD-520
May 1, 1984 ..	May 1, 1982	Drugs indicated for vertigo/motion sickness/vomiting .....	HFD-120
Do .....	.....do .....	Antidiuretics .....	HFD-510
Do .....	.....do .....	Contraceptives .....	Do.
Do .....	.....do .....	Macrolides .....	HFD-520
Do .....	.....do .....	Lincosamides .....	Do.
Do .....	.....do .....	Antiarthritics .....	HFD-150
Do .....	.....do .....	Antitussives .....	HFD-160
Do .....	.....do .....	Expectorants .....	Do.
Do .....	.....do .....	Inhalants .....	Do.
June 1, 1984	June 1, 1982	Urinary tract antiseptics .....	HFD-520
July 1, 1984 ..	July 1, 1982 ..	Chelating agents/heavy metal antagonists .....	HFD-110
Do .....	.....do .....	All other gastrointestinal drugs .....	HFD-110
Do .....	.....do .....	Antianxiety .....	HFD-120
Do .....	.....do .....	Drugs indicated for myasthenia gravis .....	HFD-120
Do .....	.....do .....	All other antiinfective drugs .....	HFD-520
Do .....	.....do .....	Bronchodilators/antiasthmatics .....	HFD-160
Aug. 1, 1984	Aug. 1, 1982	Estrogens .....	HFD-510
Do .....	.....do .....	Uterine stimulants .....	HFD-510
Do .....	.....do .....	Uterine relaxants .....	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock .....	HFD-110
Oct. 1, 1984 ..	Oct. 1, 1982	All other cardiac drugs .....	HFD-110
Do .....	.....do .....	Nasal decongestants .....	HFD-160
Nov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	

<sup>1</sup> Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).

<sup>2</sup> Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

## Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

### § 201.60 Principal display panel.

The term *principal display panel*, as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type

size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however*, That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms